

MAR 6 2009

**510 (k) Summary**

(As required by 21 CFR 807.92 and 21 CFR 807.93)

**NAME OF SPONSOR:** DePuy Orthopaedics, Inc.  
700 Orthopaedic Drive  
Warsaw, Indiana 46582  
Establishment Registration Number: 1818910

**510(K) CONTACT:** Dawn Sinclair  
Regulatory Affairs Associate  
Telephone: (574) 372-5023  
Facsimile: (574) 371-4987  
Electronic Mail: [Dsincla3@its.jnj.com](mailto:Dsincla3@its.jnj.com)

**DATE PREPARED:** December 5, 2008

**PROPRIETARY NAME:** DePuy Pinnacle® Metal-on-Metal Acetabular Cup Liners

**COMMON NAME:** Acetabular Cup Prosthesis

**CLASSIFICATION:** Class III per 21 CFR 888.3330, Hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis

**DEVICE PRODUCT CODE:** 87 KWA

**SUBSTANTIALLY EQUIVALENT DEVICE(S):** DePuy Pinnacle® Metal-on-Metal Acetabular Cup Liners, K062426  
DePuy Pinnacle® Metal-on-Metal Acetabular Cup Liners, K023786  
DePuy Pinnacle® Metal-on-Metal Acetabular Cup Liners, K003523  
DePuy Pinnacle® Metal-on-Metal Acetabular Cup Liners, K002883  
Biomet® Metal-on-Metal Hip Systems, K082446

**DESCRIPTION:**

The subject of this 510(k) consists of modifications to the Instructions for Use (IFU). The following two contraindications and potential adverse effect have been added to the IFU. DePuy Orthopaedics is making these IFU revisions to comply with a request from Health Canada, as well as to update the contents to reflect current industry practice. These are the only changes to the labeling and IFU; there are no changes to the device design.

**Contraindications:**

- Use is contraindicated in cases with chronic renal failure.
- Females of childbearing age are contraindicated due to the unknown effects of elevated levels of metal ions on the fetus.

**Potential adverse effect:**

- The potential long-term biological effects of metal wear debris and metal ion production are not known.

No changes have been made to the Indications for Use or the Intended Use of this device.

**INDICATIONS AND INTENDED USE:****Indications:**

The Pinnacle Metal-on-Metal Acetabular Cup Liners are indicated for use as the acetabular component in total hip replacement procedures for patients suffering severe pain and disability due to structural damage in the hip joint from rheumatoid arthritis, osteoarthritis, post-traumatic arthritis, collagen disorders, avascular necrosis, and non-union of femoral fractures. Use of the prosthesis is also indicated for patients with congenital hip dysplasia, *protrusio acetabuli*, slipped capital femoral epiphysis and disability due to previous fusion, where bone stock is inadequate for other reconstruction techniques.

**Intended Use:**

The Pinnacle Metal-on-Metal Acetabular Cup Liners are intended for use with DePuy Pinnacle Acetabular Shells and M-Spec Co-Cr-Mo femoral heads only.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

DePuy Orthopaedics, Inc.  
% Ms. Dawn Sinclair  
Regulatory Associate, Regulatory Affairs  
700 Orthopaedic Dr.  
Warsaw, Indiana 46581

MAR 6 2009

Re: K083642

Trade/Device Name: DePuy Pinnacle Metal-on-Metal Acetabular Cup Liners

Regulation Number: 21 CFR 888.3330

Regulation Name: Hip joint, metal/metal semi-constrained, with an uncemented acetabular component, prosthesis

Regulatory Class: III

Product Code: KWA

Dated: December 8, 2008

Received: December 9, 2008

Dear Ms. Sinclair:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

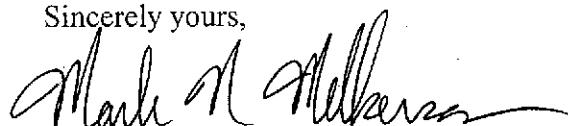
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forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Mark N. Melkerson  
Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use Statement

510 (k) Number (if known): K083642 (pg 1/1)

Device Name: DePuy Pinnacle® Metal-on-Metal Acetabular Cup Liners

### **Indications for Use:**

The Pinnacle Metal-on-Metal Acetabular Cup Liners are indicated for use as the acetabular component in total hip replacement procedures for patients suffering severe pain and disability due to structural damage in the hip joint from rheumatoid arthritis, osteoarthritis, post-traumatic arthritis, collagen disorders, avascular necrosis, and non-union of femoral fractures. Use of the prosthesis is also indicated for patients with congenital hip dysplasia, *protrusio acetabuli*, slipped capital femoral epiphysis and disability due to previous fusion, where bone stock is inadequate for other reconstruction techniques.

The Pinnacle Metal-on-Metal Acetabular Cup Liners are intended for use with DePuy Pinnacle Acetabular Shells and M-Spec Co-Cr-Mo femoral heads only.

Prescription Use X AND/OR Over-The-Counter Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

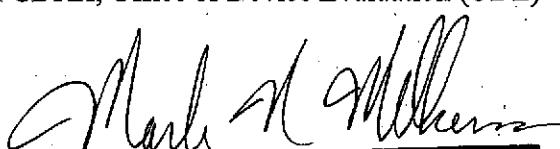
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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Posted November 13, 2003)

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(Division Sign-Off)

Division of General, Restorative,  
and Neurological Devices

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